



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 076333-0240

Applicant: Robert H. Getzenberg
Title: BLADDER CANCER NUCLEAR MATRIX PROTEINS,
POLYNUCLEOTIDE SEQUENCES ENCODING THEM, AND THEIR USE
Application No.: 09/866,927
Filing Date: May 30, 2001
Examiner: Larry Ronald Helms
Art Unit: 1642

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop NON-FEE AMENDMENT
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

I, Robert H. Getzenberg, being duly warned, hereby declare and state:

1. I am a citizen of the United States and reside at 1627 Augusta Drive, Pittsburgh, PA 15237-6702.

2. I am the named inventor of the subject matter disclosed in the United States application Serial No. 09/418,839 ("the application").

3. I am an Associate Professor at the University of Pittsburgh School of Medicine. I have been doing research and development in the field of nuclear matrix protein biology and tumor markers since 1987. Attached is my Curriculum Vitae to further explain my experience and background.

4. I understand the Examiner's position on page 4 of the final Office Action dated June 25, 2003 to be that there is a discrepancy in the molecular weight of the BLCA-6 protein. As evidenced by the cited reference (Getzenberg *et al.*, *Cancer Research* 56:1690-94, 1996), the molecular weight of the BLCA-6 is 31-kD. However, the specification incorrectly states that it has a molecular weight of 22-kD.

5. This declaration of mine is to clarify and to explain that the BLCA-6 protein in

the specification is the same as that of the cited reference.

6. At the time of preparing the instant application and other related applications (parent application, U.S. Patent No. 5,866,535 and a related application, U.S. Patent No. 6,280,956), I mistakenly disclosed the molecular weight of the human BLCA-6 protein. At the filing of the priority application, U.S. provisional application No. 60/006226, filed November 3, 1995), I had submitted a preprint to the Managing Editor of Cancer Research journal (see Appendix A) to Foley & Lardner relating to the instant invention which contained the error in molecular weight. The Managing Editor received the preprint on October 18, 1995. As indicated at page 20, Table 2 of the preprint, the molecular weight of BLCA-6 protein was 22-kD. However, at page 21, Figure 1B, a silver stained 2-D electrophoresis gel depicted a BLCA-6 protein that was above the 29-kD molecular weight protein marker. The patent application for this invention was prepared and filed based only on the text in the manuscript without a copy of the figure in the manuscript, and we did not uncover the discrepancy until after filing as described below.

7. I discovered this error only after I received a communication dated December 20, 1995, from the Managing Editor and the reviewers of the Cancer Research journal (see Appendix B). On page 1 of the Dec. 20th letter, Reviewer #1 inquired about the MW discrepancy of the BLCA-6 protein in Table 2 and Figures 1, 2B and 2C. In a letter dated January 3, 1996, I clarified this error by stating that the correct MW of BLCA-6 protein in Table 2 should be 31-kDa (see Appendix C). Unfortunately, I did not think to notify Foley & Lardner about the discrepancy.

8. The correct molecular weight and pI of the claimed human BLCA-6 protein are about 31-kDa and 8.0, respectively. The correct molecular weight and pI are both inherent properties of this protein. One of ordinary skill in the art, upon following the procedural steps for collecting the samples and performing the protein separation technique described in the application as filed, would inherently obtain a protein having a molecular weight and pI equal to about 31-kDa and 8.0, respectively.

9. I have repeated this procedure following the steps in the specification and have obtained a protein having a MW of about 31-kDa and a pI of about 8.0 (see Appendix D). Accordingly, the 31-kDa molecular weight and pI of 8.0 are inherent properties of the BLCA-6 protein that result from performing the steps in the specification as filed. These inherent properties were shown in Figure 1B of the

preprint and disclosed in the cited reference. Thus, the claimed BLCA-6 protein in the specification is the same as the BLCA-6 protein of the cited reference.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Dated: 12/22/03



Robert H. Getzenberg